Falishort 10



JUN 2 1 2002

Jonathan Wilkin, MD, Director Division of Dermatologic and Dental Drug Products Food and Drug Administration Center for Drug Evaluation and Research Office of Drug Evaluation V, HFD-540 Atm: DOCUMENT CONTROL ROOM N115 9201 Corporate Boulevard Rockville, MD 20850

IND 21,542

Miconazole Nitrate Diaper Rash Ointment

Serial No.: 019

Transfer of Ownership

Dear Dr. Wilkin:

Reference is made to the Investigational New Drug 21,542 for Miconazole Nitrate Diaper Rash Ointment and to 21 CFR314.72 Transfer of Ownership.

This correspondence will serve as the official notification of the Transfer of Ownership of the referenced Investigational New Drug from:

Johnson & Johnson Consumer Companies, Inc. 199 Grandview Road Skillman, New Jersey 08558

To

Barrier Therapeutics 100, Overlook Center (2nd Floor) Princeton, NJ 08540

and will be effective the date of this correspondence.

This transfer of ownership includes:

- Transfer of a complete copy of the filed IND and all applicable subsequent filings.
- Transfer of all agreements, promises and conditions made by the former application holder to Barrier Therapeutics.

All future applicant inquiries should be forwarded to the new IND holder, Barrier Therapeutics.

If you have any questions, I can be reached at (908) 874-1239 or Stephanie Davis can be reached at (908) 874-2410.

Thank you.

Sincerely,

George Latyszonek

Director, Regulatory Affairs

BARRIER THERAPEUTICS, INC.

100 OVERLOOK CENTER, 2ND FLOOR PRINCETON, NJ 08540 TEL: 609-375-2200 FAX: 609-375-2660

June 21, 2002

Jonathan Wilkin, MD, Director Division of Dermatologic and Dental Drug **Products** Food and Drug Administration Center for Drug Evaluation and Research Office of Drug Evaluation V, HFD-540 Attn: DOCUMENT CONTROL ROOM N115 9201 Corporate Boulevard Rockville, Maryland 20850

IND 21,542 Miconazole Nitrate Diaper Rash **Ointment**

Serial No.: 020

Acceptance of IND Ownership and Responsibility

Dear Dr. Wilkin:

This is to inform you that effective the date of this letter Barrier Therapeutics accepts the ownership of and responsibility for the management of Investigational New Drug Application 21,542, Miconazole Nitrate Diaper Rash Ointment. Barrier Therapeutics has access to a complete copy of IND 21,542 and correspondence pertaining thereto.

Please address future correspondence concerning this Investigational New Drug Application to me at:

Barrier Therapeutics 100, Overlook Center (2nd Floor) Princeton, NJ 08540

Should you have any questions, please contact me directly at (609) 375-2280.

Sincerely,

Geen Cauwenbergh, Ph.D. Chief Executive Officer

Enclosure

Form FDA 1571